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10/634,742	08/04/2003	Michael Spaid	100/15901	6619

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EXAMINER	
YANG, NELSON C	
ART UNIT	PAPER NUMBER
1641	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/634,742	SPAID ET AL.	
	Examiner	Art Unit	
	Nelson Yang	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11/16/06*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-6,8,10-15,17-26,30-32 and 51-69* is/are pending in the application.

4a) Of the above claim(s) *8,19 and 26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-6,10-15,17,18,20-25,30-32 and 51-69* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Applicant's amendment of claims 1, 3-5, 10-15, 17, 20-22, 30, 32 is acknowledged and has been entered.

2. Applicant's addition of claims 51-69 is acknowledged and has been entered.

3. Applicant's cancellation of claims 2, 7, 9, 16, 27-29, 33-50 is acknowledged and has been entered.

4. Claims 1, 3-6, 10-15, 17, 18, 20-25, 30-32, 51-69 are currently under examination.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. With respect to claims 3, 66, it is unclear whether the dispersion of the first or second plurality of molecules is being compared with both the dispersion of the first and second plurality of molecules in the absence of the other plurality of molecules, or if the dispersion of the first plurality is compared with the dispersion of the first plurality in the absence of the second plurality, and vice versa. Further clarification would be appreciated. Currently, the latter interpretation is assumed.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1, 3, 4, 6, 11-13, 15, 17, 18, 20, 21, 25, 30, 31, 32, 51-58, 62-67 are rejected under 35 U.S.C. 102(e) as being anticipated by Chow et al. [US 6,613,580].

With respect to claims 1, 11, 51, 65 Chow et al. teach determining the effects of non-competitive inhibition reactions (column 9, lines 50-60) by determining the dispersion profile of starting material during a reaction (column 5, lines 35-40) in streams that are flowed through a channel using pressure based flow elements (column 37, lines 50-55), wherein the starting material may be enzymes and substrates (column 3, lines 35-45).

9. With respect to claim 3, Chow et al. teach that the method may be compared with a control, i.e. such as in the absence of a test modulator composition (column 21, lines 45-55) or a substrate (column 21, lines 60-65).

10. With respect to claim 4, Chow et al. teach measuring the concentration of the molecules involved in the reactions (column 25, lines 13-37).

11. With respect to claim 6, Chow et al. teach that the interactions may be binding reactions such as receptor-ligand binding (column 21, lines 45-55).

12. With respect to claim 12, the streams flow through the channels continuously (column 37, lines 40-45).

13. With respect to claim 13, Chow et al. teach that aliquots (bolus) of a fluidic material containing a test material may be introduced into the channel (column 2, lines 20-30).

14. With respect to claims 15, Chow et al. teach that the test materials may be mixed with a target material (column 4, lines 60-67) and introduced into the channel simultaneously in aliquots (boluses) column 5, lines 1-10).

15. With respect to claim 17, Chow et al. teach measuring the concentration of the molecules involved in the reactions (column 25, lines 13-37), which would be one of the plurality of the molecules.

16. With respect to claim 18, the detection may be by fluorescence (column 7, lines 25-31).

17. With respect to claim 20, Chow et al. teach that the method may be compared with a control, i.e. such as in the absence of a test modulator composition (column 21, lines 45-55) or a substrate (column 21, lines 60-65), which would be the second plurality of molecules.

18. With respect to claim 21, Chow et al. teach that the method may be compared with a control, i.e. such as in the absence of a test modulator composition (column 21, lines 45-55) or a substrate (column 21, lines 60-65), which would be the first plurality of molecules.

19. With respect to claim 25, Chow et al. teach that the interactions may be binding reactions such as receptor-ligand binding (column 21, liens 45-55).

20. With respect to claim 30, Chow et al. teach that interactions may involve a three plurality of molecules (the two components involved in the reaction, and a modulator) (column 21, lines 45-50).

21. With respect to claim 31, Chow et al. determining the dispersion profile of starting material during a reaction (column 5, lines 35-40) in streams that are flowed through a channel (which would be in the longitudinal direction) using pressure based flow elements (column 37, lines 50-55).

22. With respect to claim 32, the pluralities of molecules are not flowed in side by side streams (see. Fig. 3, dispersed sample). Chow et al. further teach that fluidic material containing a test material may be introduced into the channel (column 2, lines 20-30) in aliquots, which would not be in side-by-side streams.

23. With respect to claim 52, the streams flow through the channels continuously (column 37, lines 40-45).

24. With respect to claim 53, Chow et al. teach that aliquots (bolus) of a fluidic material containing a test material may be introduced into the channel (column 2, lines 20-30).

25. With respect to claims 54, 55, Chow et al. teach that the test materials may be mixed with a target material (column 4, lines 60-67) and introduced into the channel simultaneously in aliquots (boluses) column 5, lines 1-10).

26. With respect to claim 56, Chow et al. teach measuring the concentration of the molecules involved in the reactions (column 25, lines 13-37), which would be one of the plurality of the molecules.

27. With respect to claim 57, Chow et al. teach that the method may be compared with a control, i.e. such as in the absence of a test modulator composition (column 21, lines 45-55) or a substrate (column 21, lines 60-65), which would be the second plurality of molecules.

28. With respect to claim 58, Chow et al. teach that the method may be compared with a control, i.e. such as in the absence of a test modulator composition (column 21, lines 45-55) or a substrate (column 21, lines 60-65), which would be the first plurality of molecules.

29. With respect to claim 62, Chow et al. teach that interactions may involve a three plurality of molecules (the two components involved in the reaction, and a modulator) (column 21, lines 45-50).

30. With respect to claim 63, Chow et al. determining the dispersion profile of starting material during a reaction (column 5, lines 35-40) in streams that are flowed through a channel (which would be in the longitudinal direction) using pressure based flow elements (column 37, lines 50-55).

31. With respect to claim 64, the pluralities of molecules are not flowed in side by side streams (see. Fig. 3, dispersed sample). Chow et al. further teach that fluidic material containing a test material may be introduced into the channel (column 2, lines 20-30) in aliquots, which would not be in side-by-side streams.

32. With respect to claim 66, Chow et al. teach that the method may be compared with a control, i.e. such as in the absence of a test modulator composition (column 21, lines 45-55) or a substrate (column 21, lines 60-65), which would be the first plurality of molecules.

33. With respect to claim 67, Chow et al. teach measuring the concentration of the molecules involved in the reactions (column 25, lines 13-37), which would be one of the plurality of the molecules.

34. Claims 1, 3-6, 51, 52, 54, 56-58, 62, 63 are rejected under 35 U.S.C. 102(b) as being anticipated by Hatch et al. [Hatch et al., A rapid diffusion immunoassay in a T-sensor, May 2001, Nat Biotech, 19, p.461-465].

With respect to claims 1, 51, Hatch et al. teach measuring the diffusion profile of labeled antigen, which is affected by the concentration of competing sample antigen as the sample antigens compete for binding sites on antibodies (p.462, col.1-2). In this embodiment, the sample antigen or labeled antigen would be one of the plurality of molecules, while the antibody would be the other plurality of molecules. Hatch et al. further teach that this allows the measurement of either the concentration of analyte or the affinity of molecules involved in the binding reaction (p.461, col.2). Although Hatch et al. describes the measurement of the diffusion of the molecule, this measurement is performed by measuring the concentration of analyte (p.461, col.2), which is the technique used by applicants to measure the dispersion. Therefore, it appears that the dispersion and diffusion of the molecule are the same.

35. With respect to claim 3, the diffusion profile measured is compared with that of one for a freely diffusing antigen (p.462, col.1).

36. With respect to claim 4, Hatch et al. teach the measurement of either the concentration of analyte or the affinity of molecules involved in the binding reaction (p.461, col.2).

37. With respect to claim 5, neither the sample antigens nor the antibodies are labeled (p.462, col.1). Instead a third plurality of molecules are labeled.

38. With respect to claim 6, the interaction taught by Hatch et al. is a binding reaction (p.462, col.1-2), which would be associative.

39. With respect to claim 52, Hatch et al. teach that the molecules are introduced into the channel in solutions pumped through the inlets at equal constant flow rates (p. 461, col.2), which would result in a continuous stream.

40. With respect to claim 54, Hatch et al. disclose that the molecules are introduced simultaneously through two inlets (p.462, fig. 1).

41. With respect to claim 56, Hatch et al. teach the measurement of either the concentration of analyte or the affinity of molecules involved in the binding reaction (p.461, col.2).

42. With respect to claim 57, the diffusion profile measured is compared with that of one for a freely diffusing antigen (p.462, col.1). In this situation the antigen would be considered the first plurality of molecules.

43. With respect to claim 58, the diffusion profile measured is compared with that of one for a freely diffusing antigen (p.462, col.1). In this situation the antigen would be considered the second plurality of molecules.

44. With respect to claim 62, Hatch et al. teach measuring the diffusion profile of labeled antigen (addition plurality of molecules), which is affected by the concentration of competing sample antigen (first plurality of molecules) as the sample antigens compete for binding sites on antibodies (second plurality of molecules) (p.462, col.1-2).

45. With respect to claim 63, the diffusion measured is sample broadening as the sample travels downstream (longitudinal direction) (p.462, fig. 2).

Claim Rejections - 35 USC § 103

46. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

47. Claims 10, 22-24, 59-61, 69, are rejected under 35 U.S.C. 103(a) as being unpatentable over Chow et al. [US 6,613,580].

With respect to claims 10, 59-61, 69, Chow et al. teach molecules with diffusion ratios but fail to specifically teach diffusivity ratios of at least about 2, about 8-10, or greater than 10. However, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranged involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Therefore, it would have been obvious in the method of Hatch et al. for the diffusivity ratios of the first and second plurality of molecules to be at least about 2, about 8-10, or greater than 10 through normal optimization procedures in the art.

48. Claims 10, 59-61, are rejected under 35 U.S.C. 103(a) as being unpatentable over Hatch et al. [Hatch et al., A rapid diffusion immunoassay in a T-sensor, May 2001, Nat Biotech, 19, p.461-465].

With respect to claims 10, 59-61, Hatch et al. teach molecules with diffusion ratios but fail to specifically teach diffusivity ratios of at least about 2, about 8-10, or greater than 10. However, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranged involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Therefore, it would have been obvious in the method of Hatch et al. for the diffusivity ratios of the first and second plurality of molecules to be at least about 2, about 8-10, or greater than 10 through normal optimization procedures in the art.

49. Claims 11, 12, 15, 17, 18, 20-25, 30, 31, 65-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hatch et al. [Hatch et al., A rapid diffusion immunoassay in a T-sensor, May 2001, Nat Biotech, 19, p.461-465] in view of Hefti [US 6,287874].

With respect to claims 11, 65, Hatch et al. teach measuring the diffusion profile of labeled antigen, which is affected by the concentration of competing sample antigen as the sample antigens compete for binding sites on antibodies (p.462, col.1-2). In this embodiment, the sample antigen or labeled antigen would be one of the plurality of molecules, while the antibody would be the other plurality of molecules. Hatch et al. further teach that this allows the measurement of either the concentration of analyte or the affinity of molecules involved in the binding reaction (p.461, col.2). Hatch et al. do not teach that the first and second plurality of molecules comprise an enzyme and substrate.

Hefti, however, teaches the measurement of enzyme/substrate interactions (column 6, lines 23-45) involving measurement of dispersion effects (column 26, lines 1-5). Hefti further provides motivation for doing so by teaching that proteins play a variety of key roles in biological processes, and that by screening large libraries of compounds for their ability to bind protein targets of interest, ligands identified as binding to the target can be used to develop more focused libraries, resulting in the identification of lead compounds that are subjected to various pharmaceutical analyses to select useful drug candidates (column 1, lines 45-67).

Therefore, it would have been obvious to one of ordinary skill in the art to study the interaction of enzymes and substrates, in the method of Hatch et al., as suggested by Hefti, in

order to identify lead compounds that can be subjected to various pharmaceutical analyses to select useful drug candidates.

50. With respect to claim 12, Hatch et al. teach that the molecules are introduced into the channel in solutions pumped through the inlets at equal constant flow rates (p. 461, col.2), which would result in a continuous stream.

51. With respect to claim 15, Hatch et al. disclose that the molecules are introduced simultaneously through two inlets (p.462, fig. 1).

52. With respect to claim 17, Hatch et al. teach the measurement of either the concentration of analyte or the affinity of molecules involved in the binding reaction (p.461, col.2).

53. With respect to claim 18, the detection may be based on fluorescence intensity (p.463, col.1).

54. With respect to claim 20, the diffusion profile measured is compared with that of one for a freely diffusing antigen (p.462, col.1). In this situation the antigen would be considered the first plurality of molecules.

55. With respect to claim 21, the diffusion profile measured is compared with that of one for a freely diffusing antigen (p.462, col.1). In this situation the antigen would be considered the second plurality of molecules.

56. With respect to claims 22-24, Chow et al. teach molecules with diffusion ratios but fail to specifically teach diffusivity ratios of at least about 2, about 8-10, or greater than 10. However, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranged involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Therefore, it would have been obvious in the method of Hatch et al. for the diffusivity ratios of the first and second plurality of molecules to be at least about 2, about 8-10, or greater than 10 through normal optimization procedures in the art.

57. With respect to claim 25, the interaction taught by Hatch et al. is a binding reaction (p.462, col.1-2), which would be associative.

58. With respect to claim 30, Hatch et al. teach measuring the diffusion profile of labeled antigen (addition plurality of molecules), which is affected by the concentration of competing sample antigen (first plurality of molecules) as the sample antigens compete for binding sites on antibodies (second plurality of molecules) (p.462, col.1-2).

59. With respect to claim 31, the diffusion measured is sample broadening as the sample travels downstream (longitudinal direction) (p.462, fig. 2).

60. With respect to claim 66, the diffusion profile measured is compared with that of one for a freely diffusing antigen (p.462, col.1).

61. With respect to claim 67, Hatch et al. teach the measurement of either the concentration of analyte or the affinity of molecules involved in the binding reaction (p.461, col.2).

62. With respect to claim 68, neither the sample antigens nor the antibodies are labeled (p.462, col.1). Instead a third plurality of molecules are labeled.

63. With respect to claim 69, Hatch et al. teach molecules with diffusion ratios but fail to specifically teach diffusivity ratios of at least about 2. However, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranged involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Therefore, it would have been obvious in the method of Hatch et al. for the diffusivity ratios of the first and second plurality of molecules to be at least about 2 through normal optimization procedures in the art.

Double Patenting

64. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 11, 51, 65 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 20, 22, 27 of U.S. Patent No. 6,613,580. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent discloses a method of detecting the effects of a modulator on the interaction of two compounds. Since the claims recited use open ended language (comprising) and recite the use of two plurality of molecules, the method taught by the patent would be a species that would render the broader genus method taught by the instant claims obvious.

Response to Arguments

65. Applicant's arguments with respect to claims 1, 3-6, 10-15, 17, 18, 20-25, 30-32, 51-69 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

66. No claims are allowed.

67. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

68. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571) 272-0826. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nelson Yang
Patent Examiner
Art Unit 1641

LONG V. LE 07/01/07
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